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Section II

510(k) SUMMARY

Submitted by:	Kosin Technologies, LLC. 3305 Greyfox Drive Valparaiso, IN 46383 Phone: (219) 508-3419
	Small Business Decision No.: **SBD047023** Expires: Sep, 30, 2004
	Payment Identification No.: **012216-956733**
Contact Person:	Avtar S. Dhindsa, M.D.
Date Prepared:	January 14, 2004
Proprietary Name:	Piggyback Irrigating System
Common Name:	Endoscope Irrigation Tubing Set
Classification Name:	Endoscope And/Or Accessories
Predicate Device:	C.R. Bard Syringe Assist Irrigation 510(k) #K905102

Description of the Device:
The I.V. Piggyback Irrigating System is designed with a releasably mounted modular endoscope valve assembly. It is designed for controlled irrigation through an endoscope during urological and/or endoscopic procedures. The design of the valve allows the irrigation to be controlled between the finger and the thumb of the hand holding the endoscope, leaving the other hand completely free for stone extraction, lithotripsy, or biopsy.

Intended Use of the Device:
The device is intended for use in the irrigation of the ureter and renal pelvis during therapeutic and diagnostic ureteroscopy and/or endoscopic procedures.

Technological Characteristics:
The Piggyback Irrigating System is substantially equivalent to the Bard *Syringe Assist Irrigation* under 510(k) number K905102. It has the same intended use, and is manufactured from similar biocompatible materials as the predicate device.

Performance Data:
Comparative performance testing was done, between the proposed Piggyback Irrigating System and the current C.R. Bard Syringe Assist Irrigation System. Data summaries and results from the testing are included in Table 1.

A biocompatibility assessment was performed on the materials with satisfactory results. Test results are included in Appendix B.

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Table 1. Device Comparison Information – Similarities and Differences

	Kosin **Piggyback Irrigating System**	**C.R. Bard** **Syringe Assist Irrigation System**
Intended Uses	This device is intended for use in the irrigation of the ureter and renal pelvis during the therapeutic and diagnostic ureteroscopy/ureteropyescopy. Once the valve assembly is mounted to the endoscope, the physician can manually control the flow of irrigation fluid during urological and/or endoscopic procedures.	This device is intended for use in the irrigation of the ureter and renal pelvis during the therapeutic and diagnostic ureteroscopy/ureteropyescopy. It is connected to the endoscope with standard luer adapters.
Users	Hospitals, clinics, laboratories	Hospitals, clinics, laboratories
Materials	Polycabonate, nylon, PVC, thermoplastic elastomer, silicone rubber, stainless steel	Natural Rubber Latex, polycarbonate, PVC, lubricant
Lubricant composition	Medical grade silicone	Medical grade silicone
Sterility Assurance Level	10^{-6} SAL	10^{-6} SAL
Packaging material	Tyvek pouch	Tyvek pouch
Modes of irrigation	1. Continuous by gravity 2. Intermittent by depressing plunger	1. Continuous by gravity 2. Intermittent by depressing plunger
Flow Rate	- 4 foot head height = 9.8 L/hr - 6 foot head height = 12.0 L/hr - 6 foot head height = 14.4 L/hr (with pressure cuff)	- 4 foot head height = 14.7 L/hr - 6 foot head height = 17.8 L/hr - 6 foot head height = 22.9 L/hr (with pressure cuff)
Plunger activation	0.76 lbf	3.99 lbf
Single Use Only	Single Use	Single Use
Biocompatibility	Cytotoxicity Sensitization Irritation Systemic Toxicity	Same
Sterilization method	Gamma	EtO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2004

Avtar S. Dhindsa, M.D.
Kosin Technologies, LLC
3305 Greyfox Drive
VALPARAISO IN 46383

Re: K040094
Trade/Device Name: Piggyback Irrigating System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LJH
Dated: January 14, 2004
Received: January 16, 2004

Dear Dr. Dhindsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Section V

INDICATIONS FOR USE STATEMENT

510(k) Number: K040094

Device Name: Piggyback Irrigating System

Indications For Use: The device is intended for use in the irrigation of the ureter and renal pelvis during therapeutic and diagnostic ureteroscopy and/or endoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR §801.109)

Over-The-Counter Use_____

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040094